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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/649,749

08/27/2003

Kim R. Harmon

0103-0040 (ZM0574)

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10/13/2006

ZIMMER TECHNOLOGY - REEVES

P. O. BOX 708

WARSAW, IN 46581-0708

EXAMINER

SOLANKI, PARIKHA

ART UNIT

PAPER NUMBER

3737

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,749

Applicant(s)

HARMON ET AL.

Examiner

Parikha Solanki

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/27/03 and 1/24/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-20 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-13 and 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 14 and 15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/27/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8.21.2003</u>
<u>3.9.2005</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 4-13 and 16-20, drawn to a tracking array and an associated surgical navigation system.
 - II. Claim 14 and 15, drawn to a method of making a tracking array.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the surgical tracking array apparatus may be made by any one of a variety of manufacturing processes, and as such the method of making established in claims 14 and 15 is considered a patentably distinct invention.
3. During a telephone conversation with Cary Reeves on 25 September 2006, a provisional election was made without traverse to prosecute claims 4-13 and 16-20, drawn to the invention of a tracking array and an associated surgical navigation system. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14 and 15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 16 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of copending Application No. 11/039,040. Although the conflicting claims are not identical, they are not patentably distinct from each other because they all describe a surgical navigation array having a body and a plurality of tracking elements mounted to the body, the position of at least one element being adjustable to produce alternate spatial arrays of tracking elements. Claims 17-20 of the instant application are also rejected on the ground of nonstatutory obviousness-type double patenting in view of their dependence on claim 16.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

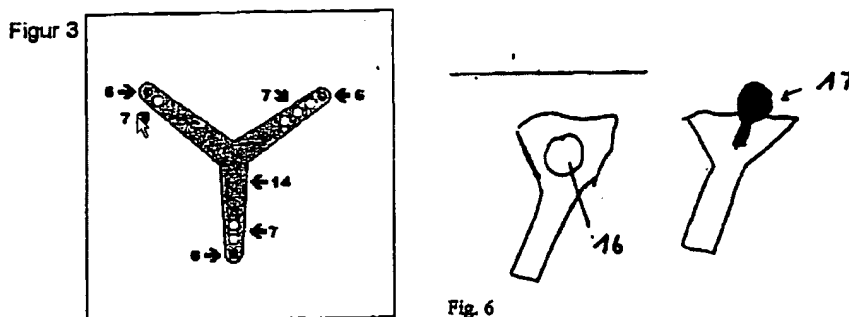
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 4-6, 8-13 and 16-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Marmulla (US PG Pub. No. 2002/0183608), cited by Applicant in the Information Disclosure Statement.

Regarding claims 4-6, 13 and 16-20, Marmulla ('608) discloses a surgical navigation marker, equivalent to an array, having a body and a plurality of tracking elements adjustably attached to the body, for use with a surgical navigation system that includes means for detecting the position of the elements (Figs. 3 & 6, ¶ 0022). Marmulla ('608) also discloses that at least three arrays may be attached to the patient during surgery (¶ 0025). Marmulla ('608) further discloses that the spatial characteristics of the array may be used to uniquely identify the position of the array (¶ 0033). The array of Marmulla ('608) has a plurality of tracking element attachment locations, which may outnumber the tracking elements attached to the array (Fig.

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3). The number of tracking elements of Marmulla ('608) may also be chosen so as to ensure that the array to which the elements are attached is still uniquely identifiable in the event that one of the tracking elements is blocked from detection (Fig. 3). Marmulla ('608) discloses that the tracking elements may comprise planar reflective surfaces (§ 0022).



(Source: Marmulla et al, US PG Pub. No. 2002/0183608)

Regarding claim 8, Marmulla ('608) shows that the array body may include a cylindrical recess at the attachment locations, engageable with cylindrical members of the tracking elements (Figs. 3 & 6).

Regarding claims 9-12, Marmulla ('608) discloses that the tracking elements may be LEDs, reflectors, ultrasound transmitters, or electromagnetic transmitters (§ 0022).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marmulla ('608). Marmulla ('608) anticipates all limitations of the present invention as described above, with the exception of disclosing that the array is made of a polymer. Marmulla ('608) is in fact silent with respect to the material composition of the array. However, it would have been an obvious design choice to create the array from a polymer, as polymers are widely used in surgical devices

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for their biocompatibility and ease of manufacture. Therefore, it would have been obvious to one of ordinary skill in the art to mold the array of Marmulla ('608) from a polymer.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rossner (US PG Pub. No. 2003/025329) and Barnett (US Pat. No. 5,904,691) disclose related tracking devices with adjustable markers for use with a surgical navigation system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Parikha Solanki
Examiner
Art Unit 3737



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